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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,333	03/06/2002	Paz Einat	EINAT1.1D	1554

1444 7590 06/15/2005

BROWDY AND NEIMARK, P.L.L.C.  
624 NINTH STREET, NW  
SUITE 300  
WASHINGTON, DC 20001-5303

EXAMINER

ASHEN, JON BENJAMIN

ART UNIT PAPER NUMBER

1635

DATE MAILED: 06/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/091,333	EINAT ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Jon B. Ashen	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 March 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 12-39 is/are pending in the application.
- 4a) Of the above claim(s) 12-16 and 24-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>03/22/2002</u> .  | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Status of the Application***

1. Claims 12-39 are pending in this application. Claims 12-16 and 24-39 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 10/28/04, which requirement was made FINAL in the Action mailed 12/28/2004. Claims 17-23 are currently under examination in this application.

### ***Objections to the Specification***

#### ***Sequence Compliance***

2. The disclosure is objected to because of the following: This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Figure 6 of the specification as filed contains two nucleotide sequences of over 10 nucleotide residues each which do not comply with the requirements above, in particular 1.821(d) at least, wherein they are set forth without accompanying sequence identifiers. The brief description of the drawings does not contain these sequence identifiers. In order to be fully responsive to this Office Action, Applicant should review

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this application in its entirety to ensure compliance with the requirements of 37 CFR 1.821 through 1.825 and to make all appropriate corrections. In the instant case, because the sequences depicted as mouse and human could be identified by reference to the sequence listing, examination of the Application was not precluded. Inclusion of the appropriate sequence identifiers, by proper amendment to the brief description to the drawings, would be remedial.

#### ***Election/Restrictions***

3. Applicant's arguments with regard to the Requirement for Restriction mailed 09/30/2004 have not been considered because this requirement was made final in the Action mailed 12/28/2004.

#### ***Information Disclosure Statement***

4. The PTO form 1449 (IDS) filed on 03/06/02 has been considered and the references listed therein made of record.

#### ***Claim Rejections - 35 USC § 112***

5. Claims 20 and 22 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons set forth in the Action mailed 12/28/2004, because claims 20 and 22 introduce new matter.

***Response to Arguments***

6. Applicant's arguments filed 03/28/2005 have been fully considered but they are not persuasive. Applicant has argued that the language of page 23, lines 21-24 of the present specification, which states: "AS [antisense] oligonucleotide sequences may be short sequences of DNA, typically 15-30 mer, but may be as small as 7 mer (Wagner et al, 1996), designed to complement a target mRNA of interest and form an RNA:AS duplex" provides support for the claim drawn to an RNA molecule that is an antisense RNA. Applicant has also pointed to page 24, lines 7-10, that states: "An additional mode the interaction of action results from AS with genomic DNA to form a triple helix that may be transcriptionally inactive" and that this provides support for an RNA molecule that targets DNA encoding a polypeptide of SEQ ID NO: 10. However, contrary to Applicant's argument, the language pointed to in the instant specification provides support for antisense (AS) that is DNA, not RNA, wherein that DNA forms a RNA:AS duplex (an RNA:DNA duplex) wherein that AS DNA can interact to form a triple helix.

Therefore, claims to an RNA molecule that is an antisense RNA or for an RNA molecule that targets DNA do not find support in the specification as filed and are considered new matter.

***Claim Rejections - 35 USC § 102 or 35 USC § 103***

7. Claims 17-20 and 22-23 remain rejected under 35 U.S.C. 102(e) or 35 USC 103(a) as being anticipated by or obvious over Chang (U.S. Patent 5,912,326) for the reasons set forth in the Action mailed 12/28/2004.

***Response to Arguments***

8. Applicant's arguments filed 03/28/2005 have been fully considered but they are not persuasive. Applicant has noted (pg. 4, ultimate paragraph) that, "The examiner states that the 5' end of the 19 nucleobase oligonucleotide of Chang is 100% identical over the first sixteen contiguous nucleobases, to the polypeptide of SEQ NO:10 of the present invention" and that "This statement is rather confused, as nucleobases cannot correspond to polypeptides. The examiner thanks Applicant for pointing out an apparent misstatement which, for the purposes of clarification, should have stated, "The 5' end of the 19 nucleobase oligonucleotide of Chang is 100% identical, over the first 16 contiguous nucleobases, to the nucleic acid molecule (SEQ ID NO: 2) encoding the polypeptide of SEQ ID NO: 10 of the instant invention.

Applicant has argued that it is apparent that the portion of SEQ ID NO: 2 that is identical to the oligonucleotide of Chang (as above) corresponds exactly to the first 16 nucleobases of SEQ ID NO: 15 at positions 19-34 but that the coding region within SEQ ID NO: 2 is at positions 219, 200 and 221. Applicant has then argued that, "Claim 17 requires that the RNA molecule target mRNA encoding a polypeptide having the amino acid sequence of SEQ ID NO:10. The nucleobases at positions 19-34 of SEQ ID NO:2

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are upstream of the coding region, and therefore do not encode a polypeptide having the amino acid sequence of SEQ ID NO:10. These nucleobases will not bind an mRNA encoding the polypeptide as they will not appear in the mRNA, which includes only the coding region of the gene" and that, "The same is true with respect to claim 22...." (pg. 5, 1<sup>st</sup> full paragraph). However, Applicant appears to be arguing limitations that do not appear in the instant claims. Claim 17 recites, An RNA molecule which targets mRNA encoding a polypeptide having the amino acid sequence of SEQ ID NO: 10." The oligonucleotide of Chang would therefore be an RNA molecule targeted to the mRNA or DNA encoding the polypeptide of SEQ ID NO: 10 of the instant invention, as set forth in the prior Action, because an mRNA transcript is an mRNA encoding a polypeptide, as claimed, and is recognized in the art as encompassing not only those nucleobases which form the coding region of the transcript but also the 5' untranslated region and the 3' untranslated region of the mRNA transcript.

9. Claims 17-20 and 22-23 remain rejected under 35 U.S.C. 102(a) or 35 USC 103(a) as being anticipated by or obvious over Sutcliffe et al. (W0 98/05352) for the reasons set forth in the Action mailed 12/28/2004.

### ***Response to Arguments***

10. Applicant's arguments filed 03/28/2005 have been fully considered but they are not persuasive. Applicant has noted, on pg. 6, 2<sup>nd</sup> full paragraph, that the listing of Sutcliffe has only 13 sequences but that in reviewing Sutcliffe et al. , a 20 nucleobase

primer at pg. 71, lines 18 was located that is 100% identical to nucleobases 12-31 of instant SEQ ID NO: 2. The examiner thanks Applicant for pointing out the inadvertent labeling of the oligonucleotide of Sutcliffe et al., in the prior Action, with the incorrect sequence identifier and for clarifying the record to indicate that the oligonucleotide of Sutcliffe et al. that was applied can be found in the prior art reference at page 71, line 18. Applicant has applied the same argument to the rebuttal of the outstanding rejection over Sutcliffe et al., as was applied above in their rebuttal of the outstanding rejection under Chang (pg. 6, 2<sup>nd</sup> full paragraph). The rebuttal of the outstanding rejection over Sutcliffe et al. is not persuasive for the reasons set forth above in section 8, the response to arguments presented as rebuttal of the outstanding rejection under Chang.

11. Claims 17-23 remain rejected under 35 U.S.C. 102(e) or 35 USC 103(a) as being anticipated by or obvious over Pavco et al. (U.S. Patent 6,818,447) for the reasons set forth in the Action mailed 12/28/2004.

### ***Response to Arguments***

12. Applicant's arguments filed 03/28/2005 have been fully considered but they are not persuasive. Applicant has noted that they have been unable to determine which portion of the sequence encoding the polypeptide of SEQ ID NO: 10 is targeted by the ribozyme (SEQ ID NO: 7749) of Pavco et al. and has requested that the examiner specifically refer to the nucleotide numbers from instant SEQ ID NO: 2 (pg. 7, final



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paragraph bridge to pg. 8, 1<sup>st</sup> partial paragraph). Applicant's attention is directed to nucleotide positions 1382 to 1398 of instant SEQ ID NO: 2 which shares 94.1% complementarity, including 100% identity over the first 5 nucleobases from each of the 5' and 3' ends of each binding arm, with the ribozyme (SEQ ID NO: 7749) of Pavco et al.. In response to Applicant's apparent concern that the ribozyme of Pavco et al. is applied to the region of instant SEQ ID NO: 2 that is the poly A tail, the Examiner notes here that the poly A tail at the end of instant SEQ ID NO: 2 is not referred to and arguments in regards to the poly A tail are therefore considered moot. Nucleotide positions 1382 to 1398 of instant SEQ ID NO: 2 are within an mRNA that encodes a polypeptide having an amino acid sequence of SEQ ID NO: 10, as required by the claims.

13. Applicants note, on pg. 8, 1<sup>st</sup> full paragraph, that the additional art made of record in the Action mailed 12/28/2004, but not relied upon, has been noted, as has the implicit recognition that it is insufficiently pertinent to warrant its application against the claims. However, this statement appears to be an inadvertent mischaracterization of what was intended and set forth. The prior art made of record and not relied upon but considered pertinent to applicant's disclosure that was set forth in the Action mailed 12/28/2004 was listed as a courtesy to Applicant, to indicate that a wide variety of prior art could be applied against the instant claims, but was not, in the instant case, so applied in the interests of compact prosecution and so as to not bury Applicant in rejections that required a response. There was no implicit or explicit recognition that this prior art was

insufficiently pertinent to warrant its application against the claims because the statement as it appeared in the prior Action clearly sets forth that the prior art made of record but not relied upon is considered pertinent.

### ***Conclusion***

14. No claims are allowed.

15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon B. Ashen whose telephone number is 571-272-2913. The examiner can normally be reached on 7:30 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone


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number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Jba



**ANDREW WANG**  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600